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| APPLICATION NO.                           | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|-----------------|----------------------|-------------------------|------------------|
| 10/719,632                                | 11/21/2003      | Robert C. O'Brien    | 31611.0028              | 3465             |
| 33751                                     | 7590 04/06/2006 | EXAMINER             |                         | INER             |
|   | GREATBATCH TEC  | FAULCON JR, LENWOOD  |                         |                  |
| 10,000 WEHRLE DRIVE<br>CLARENCE, NY 14031 |                 |                      | ART UNIT                | PAPER NUMBER     |
|   | •               |                      | 3762                    |                  |
|   |                 |                      | DATE MAILED: 04/06/2006 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)  |  |  |  |
|---|---|---|--|--|--|
|   | 10/719,632  | O'BRIEN ET AL.  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit  |  |  |  |
|   | Lenwood Faulcon, Jr.  | 3762  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |   |   |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period v  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | l. lely filed the mailing date of this communication. |  |  |  |
| Status  |   |   |  |  |  |
| Responsive to communication(s) filed on <u>20 December</u> This action is <b>FINAL</b> . 2b) ☐ This      Since this application is in condition for allower closed in accordance with the practice under E  | action is non-final.<br>nce except for formal matters, pro  |   |  |  |  |
| Disposition of Claims   |   |   |  |  |  |
| 4) ⊠ Claim(s) <u>1-26</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) <u>1-26</u> is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or   | vn from consideration.  |   |  |  |  |
| Application Papers  |   |   |  |  |  |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomplicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Example.  | epted or b) objected to by the Eddrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj   | e 37 CFR 1.85(a).<br>ected to. See 37 CFR 1.121(d).   |  |  |  |
| Priority under 35 U.S.C. § 119  |   |   |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |   |   |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  | 4) Interview Summary  |   |  |  |  |
| <ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)</li> <li>Paper No(s)/Mail Date</li> </ul>  | Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:   | atent Application (PTO-152)                           |  |  |  |

### **DETAILED ACTION**

## Response to Arguments

1. Applicant's arguments filed December 20, 2005 have been fully considered but they are not persuasive.

Applicant asserts that the nanosensor as taught by Lieber et al. is not capable of being implantable in direct contact with body tissue; however, Examiner disagrees.

Examiner takes the position that Lieber et al. teaches of a nanosensor being used as an implantable nanosensor (paragraph 162); therefore, the nanosensor as taught by Lieber et al. is inherently capable of being imbedded/implanted in body tissue.

Applicant also asserts that the covalent bonding of the nanotube as claimed by Applicant, is not taught by Lieber et al.; however, Examiner disagrees. Examiner takes the position Lieber et al. teaches of a nanowire/nanotube that has a "sidewall having a length extending to first and second ends" (figures 1b and 16a). Examiner also takes the position that the covalent bond as taught by Lieber et al. (paragraphs 68, 72) extends on the "surface" of the nanotube (paragraphs 158-160) to at least a portion of the nanotube "end" (figure 16) as defined by Applicant.

Further, Examiner takes the position that claims 1, 11, 14, 20 and 25, contain language that is in the alternative as it relates to the limitation of the nanotubes being covalently bonded to the substrate at both their first and second ends, and subsequently this limitation and those that follow such language are not a positive limitation.

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For the reasons set forth in the previous Office Action of November 2, 2005, and further reiterated below, Malonek et al. is obvious over claims 1-5, and 10 in view of Lieber et al., Malonek et al. is also obvious over claims 6, 7, 14-19 and 25-26 in view of Lieber et al. and Smalley et al., and Malonek et al. is further obvious over claims 8, 9 and 11-13, 20-24 in view of Lieber et al. and Croci et al.

### Claim Rejections - 35 USC § 103

2. Claims 1-5, and 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Malonek et al. (U.S. Patent No. 6,292,704) in view of Lieber et al. (U.S. 2002/0117659).

Malonek et al. teaches of high capacitance implantable electrodes, which comprise a substrate selected from the group of platinum, platinum-iridium, titanium and carbon (col. 3 lines 65-67). Malonek et al. further teaches of the implantable electrodes comprising a coating supported on the substrate (col. 3 lines 10-15). Malonek et al. also teaches that the coating may be selected from a group of materials including iridium oxide, titanium nitride (col. 4 lines 3-5), and the materials are inherently biocompatible and electrically conductive based on their known characteristics.

Malonek et al. further teaches of the use of metal nitrides in particle coatings (col. 1 lines 61-62) and the use of heat treatment on the substrate (col. 9 lines 11-15).

Malonek et al. teaches of methods for making implantable stimulation electrodes, which may comprise a metal substrate coated with tantalum oxide (col. 1 lines 27-37).

Malonek et al. does not teach the use of a multiplicity of carbon-containing nanotubes adhering to the coating.

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Lieber et al. teaches the use of carbon containing nanotubes, nanowires and nanorods (paragraph 79), for use in implantable medical devices, such as measurement and sensory devices (paragraph 162).

At the time of the invention it would have been obvious to one having ordinary skill in the art to combine the teachings of Malonek et al. with those of Lieber et al. Since both Malonek et al. and Lieber et al. involve the same field of endeavor, which includes implantable medical devices that utilize electrodes comprised of various substrates and coatings, they teach of analogous arts. It would have been obvious to modify the lead and methods of Malonek et al. by adhering a multiplicity of carbon-containing nanotubes to the coating for the purpose of strengthening the electrode. Therefore, it would have been obvious at the time of the invention to combine the teachings of Malonek et al. and Lieber et al. to meet the limitations of claims 1-5.

3. Claims 6, 7, 14-19 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malonek et al. (U.S. Patent No. 6,292,704) in view of Lieber et al. (U.S. 2002/0117659) as applied to claims 1-5 and 10 above, and further in view of Smalley et al. (U.S. 2002/0085968).

Smalley et al. teaches of a method for producing self-assembled objects comprising nanotubes that may be used singularly or in multiples (paragraph 16), for use in biocompatible implants (paragraph 276). Smalley et al. also teaches the use of nanotube ropes (paragraph 68). Smalley et al. further teaches of the use of nanotubes of carbon-doped boron nitride (paragraph 267). Smalley et al. also teaches of the use of binder precursors of any transition metal catalyst including iridium and platinum

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(paragraph 161), in oxidizing conditions (paragraph 166). Smalley et al. also teaches of the use of plasma assisted chemical vapor deposition process (paragraph 72) and providing throughout the process by way of a microwave (paragraph 171).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Malonek et al. and Lieber et al. as applied to claims 1-5 and 10 above, with the teachings of Smalley et al. Malonek et al., Lieber et al. and Smalley et al. teach of analogous art, since they disclose applications of implantable medical devices that utilize electrodes. Modifying the electrodes as taught by Malonek et al. and Lieber et al. with the teachings of Smalley et al. to increase the strength and durability of the electrode would have been obvious to one having ordinary skill in the art, since the various types of nanotubes are known for the strength characteristics.

4. Claims 8, 9 and 11-13, 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malonek et al. (U.S. Patent No. 6,292,704) in view of Lieber et al. (U.S. 2002/0117659) as applied to claims 1-7, 10, 14-15, 18-19 and 25-26 above, and further in view of Croci et al. (U.S. 2004/0151835).

Croci et al. teaches of a method for forming a coating film, consisting of nanotubes (paragraph 1). Croci et al. further teaches of growing the nanotubes from a reaction gas of acetylene (paragraph 66), which may also contain ammonium (paragraph 25) and the use of a hydrogen gas stream in the operation of forming the carbon nanotube coating on the substrate (paragraph 25). Croci et al. further teaches of maintaining the temperature of the substrate between 300°C and 1500°C during

formation of the nanotubes (paragraph 29) and then allowing the substrate to cool in a solution of iron nitrate, which also contains hydrogen (paragraph 51). Croci et al. further teaches of the use of nitrogen as a diluting gas (paragraph 26). Further, the limitation of cooling the nanotube coated substrate in hydrogen as stated in claim 13 lacks criticality.

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Malonek et al. and Lieber et al. as applied to claims 1-7, 10, 14-15, 18-19 and 25-26 above, with the teachings of Croci et al. Both Lieber et al. and Croci et al. deal with the problem of growing effective nanotubes by use of reaction gases, and thus are analogous arts. Modifying the reaction entity as taught by Lieber et al. (paragraph 65) with the teachings of Croci et al. would have been obvious to one having ordinary skill in the art, to increase the property characteristics of the nanotube.

#### Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cowland (U.S. Patent No. 3,722,005), Richter et al. (U.S. Patent No. 4,281,668), Parsonage et al. (U.S. Patent No. 5,338,430), Lorenz et al. (U.S. Patent No. 5,587,200), Nanci et al. (U.S. Patent No. 5,876,454), Schueller et al. (U.S. Patent No. 6,143,412), Loftus et al. (U.S. Patent No. 6,755,530), Mech et al. (U.S. 2002/0120296), Parsonage et al. (U.S. 2003/0093107), Supronowicz et al. (U.S. 2003/0153965), Motamedi et al. (U.S. 2004/0023317), Tomanek et al. (W.O. 99/40812), Chen et al. (W.O. 3/049,219).

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6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lenwood Faulcon, Jr. whose telephone number is 571-272-6090. The examiner can normally be reached on Monday-Thursday from 9 to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Lenwood Faulcon, Jr.

Angela Sykes

**Supervisory Examiner** 

angel D. Shy

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